

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kerry Zang et al.
Serial No.: 10/777,514
Filing Date: February 11, 2004
Confirmation No.: 5263
Group Art Unit: 3738
Examiner: Cheryl L. Miller
Title: **CONICAL, THREADED SUBTALAR IMPLANT**

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

The following Pre-Appeal Brief Request for Review ("Request") is being filed in accordance with the provisions set forth in the Official Gazette Notice of July 12, 2005 ("OG Notice"). Pursuant to the OG Notice, this Request is being filed concurrently with a Notice of Appeal. Applicants respectfully request reconsideration of certain rejections of the identified Claims in light of the remarks set forth below.

REMARKS

The Final Office Action mailed June 12, 2007 (the "Final Office Action") rejects Claims 40-69 under 35 U.S.C. § 112, first paragraph; Claims 40-45 and 55-60 under 35 U.S.C. § 102(b); and Claims 46-54 and 61-69 under 35 U.S.C. § 103(a). Applicants seek review in this Request of the rejections of Claims 50 and 51 under 35 U.S.C. § 103(a). Applicants do not seek review in this Request of the rejections of Claims 40-69 under 35 U.S.C. § 112, first paragraph; Claims 40-45 and 55-60 under 35 U.S.C. § 102(b); and Claims 46-49, 52-54, and 61-69 under 35 U.S.C. § 103(a).

Applicants contend that the rejections of Claims 50 and 51 under 35 U.S.C. § 103(a) contain clear legal and factual deficiencies, as described below. Applicants request a finding that these rejections are improper and that the claims are allowable.

Section 103 Rejections of Claims 50 and 51

Claims 50 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,961,524 to Crombie ("*Crombie*"). Applicants respectfully traverse these rejections.

Claim 50 is directed to a medical implant. The medical implant includes a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot. The body is tapered along at least a majority of the length. The medical implant further includes at least one continuous and uninterrupted thread formed around an exterior surface of the body and extending at least a majority of the length of the body. The thread is configured to at least partially prevent displacement of a talus without penetrating bone.

According to Claim 50, the majority of the thread includes a thread angle measuring approximately 60 degrees. The majority of the at least one thread also includes a crest width. The ratio of the crest width to the thread height is at least 0.3. The majority of the at least one thread further includes a thread root width measuring between 0.020 inches and 0.040 inches. *Crombie* does not disclose, teach or suggest each of these limitations.

The Final Office Action relies on a screw of *Crombie* to teach the medical implant including a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot. *See Final Office Action*, Page 3 (stating “*Crombie* discloses a implant (10; fig.1) *capable* of being placed in the sinus tarsi of a human”). *Crombie*, however, not only fails to even mention a human foot—let alone a sinus tarsi of a subtalar joint in a human foot—but *Crombie* also clearly fails to provide any suggestion that the screw of *Crombie* is “capable of being placed in the sinus tarsi” joint.

For example, *Crombie* does not include a single dimension, let alone a dimension that would enable the Examiner to conclude that the implant is “capable” of being placed in the sinus tarsi joint—a deficiency that even the Final Office Action recognizes. *See Final Office Action*, Page 4 (stating “*Crombie* does not however disclose specific values for the width, pitch, height, and thread angle”). Furthermore, despite the Final Office Action’s reliance on Fig. 1 of *Crombie* to reject Claim 50, *Crombie* not only discloses that the screw of *Crombie* includes an enlarged screw head—which would be problematic to place in the sinus tarsi joint, as would be recognized by one of ordinary skill in the relevant art—but Fig. 1 of *Crombie* further discloses inserting the screw in bone:

Referring to the drawing, in FIG. 1, a tapered screw of the invention is shown partially in cross-section in a preferred embodiment in which the screw is made of a bioabsorbable material and the material into which the screw is being inserted is bone.

See Crombie, Col. 3, Lines 25-29 (emphasis added). Thus, *Crombie* does not disclose, teach or suggest a medical implant having a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot.

Moreover, Claim 50 includes the limitation, “the at least one thread being configured to at least partially prevent displacement of a talus without penetrating bone.” The Final Office Action does not address this limitation with reference to any cited references, let alone *Crombie*.

Claim 51 is directed to the medical implant of Claim 50. The uniform taper of the at least one thread measures approximately 18 degrees. The thread height is approximately

0.032 inches. The root width is approximately 0.030 inches. The pitch is approximately 0.090 inches.

In rejecting Claims 50 and 51, the Final Office Action merely states:

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to have the dimensions claimed, since when the general conditions of a claim are disclosed in the prior art (constant thread height and pitch, with conical shape), it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

See Final Office Action, Page 4. The Board of Patent Appeals and Interferences, however, has limited this case to apply only when “the general concept and ranges were disclosed, and the particular ranges were at issue.” *See Ex parte Barnes*, 2007 WL 3448653, at *4 (Bd. Pat. App. & Interf. 2007) (emphasis added). As is conceded in the Final Office Action, *Crombie* fails to disclose ranges:

Crombie does not however disclose specific values for the width, pitch, height, and thread angle (thus their ratios) as claimed.

See Final Office Action, Page 4. Therefore, *In re Aller* does not apply. As a result—similar to the Board in *Ex parte Barnes* finding that the examiner had failed to establish a prima facie case of obviousness using the prior art—the Final Office Action has failed to establish a prima facie case of obviousness of Claims 50 and 51:

However, because Perry is silent as to the size or proportions of the vertical relationship between the inlet and outlet portions, and merely shows a gas burner without any ranges, dimension, etc., we find that the prior art applied by the examiner does not show the general conditions from which the optimum or workable ranges could be determined.

See Ex parte Barnes, at *4.

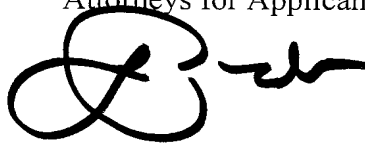
For at least this reason, Applicants respectfully submit that the rejections of Claim 50 and 51 are improper and that Claims 50 and 51 are allowable. Favorable action is requested.

CONCLUSION

As the rejections of Claims 50 and 51 contain clear deficiencies, Applicants respectfully request a finding of allowance of Claims 50 and 51. To the extent necessary, the Commissioner is hereby authorized to charge any fees or credit any overpayments to Deposit Account No. 02-0384 of BAKER BOTTS L.L.P.

Respectfully submitted,

BAKER BOTTS L.L.P.
Attorneys for Applicants

A handwritten signature in black ink, appearing to be 'L. Pedersen', written over a large, stylized circular flourish.

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Date: September 12, 2007

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